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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
KREMER, MATTHEW J	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/646,333	BRAUKER ET AL.	
	Examiner	Art Unit	
	Matthew J. Kremer	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *124-173* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *124-173* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/15/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 124-166, 168, and 171-173 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 124 recites the limitation "a porous biointerface material that covers at least a portion of the sensing region and that supports' tissue ingrowth". Claim 168 recites the limitation "a porous biointerface material covering at least a portion of the sensing region that supports tissue ingrowth". Claim 171 recites the limitation "a porous biointerface material covering at least a portion of the sensing means, wherein the porous biointerface material supports tissue ingrowth". Claim 172 recites the limitation "a porous biointerface material covering at least a portion of the analyte transport region that supports tissue ingrowth". Claim 173 recites the limitation "a porous biointerface material covering at least a portion of the analyte transport region that supports tissue ingrowth". In all these claims, there is a new limitation that includes a porous biointerface material covering at least a portion of the analyte transport/sensing region

and the same material supports tissue ingrowth. The specification supports the teaching of a porous biointerface material covering at least a portion of the analyte transport/sensing region. (for example, paragraph 0073 of the specification). The specification supports the teaching of using material that supports tissue ingrowth. (for example, the Abstract and paragraphs 0037-0038 of the specification). The Examiner could not find a teaching that the porous biointerface material covers the sensing/analyte transport region AND supports tissue ingrowth. In fact, the specification seems to imply that one material cannot provide both functions since the "biointerface material...may be placed over at least a portion (e.g., some or all) of the sensing region of the devices of the present invention to aid in preventing the formation of occlusive cells (e.g., barrier cell layer) and increasing the transport of analytes". (paragraph 0151 of the specification). If the same biointerface material also supports tissue ingrowth then the formation of occlusive cells would not be prevented and there would be a decrease in the transport of analytes, thus defeating the purpose of the biointerface material.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 124-166, 168, 170, 172, and 173 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 124 recites an "implantable sensor...the sensor comprising...a sensor body comprising a sensing region adapted for transport of an analyte between the sensor and bodily fluid". The entire claimed device is the sensor and the sensing region is part of the sensor but the claim states that the sensing region is adapted for "transport of an analyte between the sensor and the bodily fluid", which implies that the sensing region is something apart from the sensor itself. Claim 124 is rendered unclear since it is unknown what the "sensor" in the "sensing region adapted for transport between the sensor and the bodily fluid" limitation is and it is unknown if the "sensor" in this limitation is something different from the entire claimed device, which is called a sensor.

Claim 168 recites a "wholly implantable sensor...the sensor comprising...a wholly implantable body comprising a sensing region adapted for transport of an analyte between the sensor and bodily fluid". The entire claimed device is the sensor and the sensing region is part of the sensor but the claim states that the sensing region is adapted for "transport of an analyte between the sensor and the bodily fluid", which implies that the sensing region is something apart from the sensor itself. Claim 124 is rendered unclear since it is unknown what the "sensor" in the "sensing region adapted for transport between the sensor and the bodily fluid" limitation is and it is unknown if the "sensor" in this limitation is something different from the entire claimed device, which is called a sensor.

Claim 170 recites an "implantable sensor...sensor comprising...a body... comprising a sensing region adapted for transport of an analyte between the sensor and bodily fluid". The entire claimed device is the sensor and the sensing region is part of

the sensor but the claim states that the sensing region is adapted for "transport of an analyte between the sensor and the bodily fluid", which implies that the sensing region is something apart from the sensor itself. Claim 124 is rendered unclear since it is unknown what the "sensor" in the "sensing region adapted for transport between the sensor and the bodily fluid" limitation is and it is unknown if the "sensor" in this limitation is something different from the entire claimed device, which is called a sensor.

Claim 172 recites an "implantable drug delivery device...the device comprising...a body... comprising an analyte transport region adapted for transport of analytes between the device and the bodily fluid". The entire claimed invention is the device and the analyte transport region is part of the device but the claim states that the analyte transport region is adapted for "transport of analytes between the device and the bodily fluid", which implies that the analyte transport region is something apart from the device itself. Claim 124 is rendered unclear since it is unknown what the "device" in the "analyte transport region adapted for transport of analytes between the device and the bodily fluid" limitation is and it is unknown if the "device" in this limitation is something different from the entire claimed invention, which is called a device.

Claim 173 recites an "implantable cell transplantation device...the device comprising...a body comprising an analyte transport region adapted for transport of analytes between the device and the bodily fluid". The entire claimed invention is the device and the analyte transport region is part of the device but the claim states that the analyte transport region is adapted for "transport of analytes between the device and the bodily fluid", which implies that the analyte transport region is something apart from

the device itself. Claim 124 is rendered unclear since it is unknown what the "device" in the "analyte transport region adapted for transport of analytes between the device and the bodily fluid" limitation is and it is unknown if the "device" in this limitation is something different from the entire claimed invention, which is called a device.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 167 and 169 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,833,603 to Kovacs et al. (Kovacs). Kovacs teaches a sensing region 128 on a convex major surface of the body where electrodes 130 and 132 are located. (Fig. 10 of Kovacs).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 170 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,833,603 to Kovacs et al. (Kovacs) and further in view of Application Publication 2003/0114735 to Silver et al. (Silver). Kovacs discloses an implanted sensor that comprises a sensing region 128 for the transport of gases or ions. (Fig. 10 of Kovacs). Kovacs teaches the use of glass as the housing material. (column 8, lines 27-30 of Kovacs). Silver teaches that epoxy is a suitable substitute for glass. (paragraph 0203 of Silver). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the epoxy as the housing as disclosed by Silver since Kovacs teaches the use of glass and Silver teaches that epoxy is a suitable substitute for glass.

9. Claims 124, 126, and 166 are rejected under 35 U.S.C. 102(b are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,049,727 to Crothall in view of U.S. Patent 6,409,674 to Brockway et al. (Brockway). Crothall discloses an implanted sensor for measuring glucose that comprises a sensing region 104. (Fig. 8 of Crothall). Crothall does not teach the use of a biocompatible material for supporting tissue ingrowth. Brockway teaches a mesh on the outside surface of an implantable device so that an implanted device is secured at a particular location. (Figs. 3C and column 8, lines 10-57 of Brockway). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the mesh of Brockway with the invention of Crothall since the implanted sensor is secured at particular locations. In regard to claim 124, a mesh covers a portion of the sensing

region 104. (column 17, lines 62-67 of Crothall). The mesh that covers the sensing region and the mesh for the tissue ingrowth are considered the porous biointerface material.

10. Claims 124, 127-130, 132-142, 145-161, 165, 168, and 171-173 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,833,603 to Kovacs et al. (Kovacs) and further in view of U.S. Patent 6,409,674 to Brockway et al. (Brockway) and further in view of U.S. Patent 6,066,083 to Slater et al. (Slater). Kovacs discloses an implanted sensor that comprises a sensing region 128 for the transport of gases or ions. (Fig. 10 of Kovacs). Kovacs does not teach the use of a biocompatible material for supporting tissue ingrowth. Brockway teaches a mesh on the outside surface of an implantable device so that an implanted device is secured at a particular location. (Figs. 3C and column 8, lines 10-57 of Brockway). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the mesh of Brockway with the invention of Kovacs since the implanted sensors are secured at particular locations. Kovacs teaches the use of a gas-permeable membrane 126 (Fig. 10 of Kovacs) but does not teach the particulars of the membrane. Slater teaches a gas-permeable membrane made from mesh (column 7, lines 6-23 of Slater) that would fulfill the requirements of providing a membrane as set forth in the combination. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the mesh of Slater in the combination since Kovacs teaches the use of a gas-permeable membrane and Slater teaches one such

membrane. The mesh of the gas-permeable membrane and the mesh for the tissue ingrowth are considered the porous biointerface material.

In regard to claims 127-128, Kovacs disclosed an implanted sensor that comprises a continuum of sensing region 128 for the transport of gases or ions. (Fig. 10 of Kovacs). In regard to claim 129, Kovacs teaches a sensing region 128 on the left side of the housing (where electrode 130 is located) and a curved second major surface on the right side of the housing (where reference numeral 36 is located). (Fig. 10 of Kovacs). In regard to claim 130, the sensing region 128 is located on the apex of the curved first surface of the housing by virtue that the sensing region completely encapsulates the curved first surface. (Fig. 10 of Kovacs). Kovacs also teaches a curved second surface located on the right side of the sensing region on the housing (where reference numeral 36 is located). (Fig. 10 of Kovacs). In regard to claims 134-135, Kovacs teaches the use of glass as the housing material. (column 8, lines 27-30 of Kovacs). In regard to claim 138-141, Kovacs does not teach a particular radius of curvature but Kovacs does teach that the shape of the implant can be changed. This teaching provides a clear suggestion that the shape of the implant can be modified and that the determination of the most appropriate shape by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the art. In regard to claim 142, the sensing portion 128 is located on a major surface where electrodes 130 and 132 are located. In regard to claim 147-152, the sensing region is located on the first major surface on the left side of the housing. (Fig. 10 of Kovacs). The sensing region 128 is spaced away from the edges of the first major surface by at least 50% of

the width of the first major surface. In regard to claims 154-157, these claims of the present application appear to be trying to define the contour of the first major surface by referencing an imaginary reference plane. The reference plane, however, does not seem to be a physical claimed structure and can, therefore, move anywhere relative to the contoured surface within the boundaries set by the claim. The contours of the first major surface on the left side of the housing (where electrode 130 is located) of Kovacs meet these limitations because of its overall shape of the contoured surface. (Fig. 10 of Kovacs). In regard to claim 165, the bio-interface material is porous and the material is configured in such a way that the sensing region achieves equilibrium. (column 25, lines 25-35 of Kovacs). In regard to claim 171, Kovacs teaches a sensing means 128 and a housing means in the form of the capsule.

11. Claims 125 and 126 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,833,603 to Kovacs et al. (Kovacs) and further in view of U.S. Patent 6,409,674 to Brockway et al. (Brockway) and further in view of U.S. Patent 6,066,083 to Slater et al. (Slater) as applied to claim 124, and further in view of U.S. Patent Application Publication 2003/0125613 to Enegren et al. (Enegren). Kovacs teaches an implantable sensor for measuring gases and/or ions. (column 15, lines 16-45 of Kovacs). Kovacs does not teach a particular location for the implanted sensor. Enegren teaches that a pH (a measurement of hydrogen ions) can be measured in subcutaneous tissue (paragraph 0014 of Enegren), which would fulfill the requirements of providing a location for the implantable sensor as needed by Kovacs. Therefore, it

would have been obvious to one having ordinary skill in the art at the time the invention was made to implant the sensor in subcutaneous tissue as disclosed by Enegren since a location for the implantable sensor is required and Enegren teaches one such location.

12. Claims 131 and 143-144 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,833,603 to Kovacs et al. (Kovacs) and further in view of U.S. Patent 6,409,674 to Brockway et al. (Brockway) and further in view of U.S. Patent 6,066,083 to Slater et al. (Slater) as applied to claim 124, and further in view of U.S. Patent 6,454,710 to Ballerstadt et al. (Ballerstadt), and further in view of U.S. Patent 4,197,840 to Beck et al. (Beck). Kovacs teaches that the shape of the housing is cylindrical and, therefore, has a circular cross-section but Kovacs teaches that other shapes can be used. (column 8, lines 33-35 of Kovacs). Ballerstadt teaches that a rectangular cross-section is a suitable substitute for circular one. (column 8, lines 23-27 of Ballerstadt). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the rectangular cross-section for the circular cross-section since Kovacs teaches other shapes can be used and Ballerstadt teaches one such shape. The combination does not teach that the rectangular shape has rounded corners but Beck teaches that rounding of edges is necessary for implanted bodies. (column 2, lines 51-56 of Beck). The rounding of edges prevents injuries to the internal tissues of the body. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to round the edges of

the rectangular housing as disclosed by Beck since such rounding is necessary in implanted devices since such rounding prevents injuries to internal tissues.

13. Claims 162-164 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,833,603 to Kovacs et al. (Kovacs) and further in view of U.S. Patent 6,409,674 to Brockway et al. (Brockway) and further in view of U.S. Patent 6,066,083 to Slater et al. (Slater) as applied to claim 124, and further in view of Application Publication 2003/0114735 to Silver et al. (Silver). Kovacs teaches the use of glass as the housing material. (column 8, lines 27-30 of Kovacs). Silver teaches that epoxy is a suitable substitute for glass. (paragraph 0203 of Silver). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the epoxy as the housing as disclosed by Silver since Kovacs teaches the use of glass and Silver teaches that epoxy is a suitable substitute for glass.

Response to Arguments

14. Applicant's arguments with respect to claims 124-166, 168, and 171-173 have been considered but are moot in view of the new ground(s) of rejection.

15. Applicant's arguments filed 3/24/2005 have been fully considered but they are not persuasive.

In regard to claim 168, the Applicant has argued that Kovacs does not teach a major surface comprising a continuous curvature substantially across the entire surface. The Applicant asserts that Kovacs only teaches a sensor wherein the major surface does not comprise a continuous curvature, but is instead substantially flat. The Examiner respectfully disagrees. Fig. 10 of Kovacs does not show any flat surfaces on the sensor body but shows the cross-section of a generally cylindrical capsule with curved end caps. (column 8, lines 32-35 of Kovacs).

In regard to claim 169, the Applicant has argued that Kovacs does not teach a sensor comprising an electrochemical sensing region located on the first major surface that is spaced away from the rounded edges. The Applicant asserts that Kovacs only teaches a sensor wherein electrodes are situated on an end of an electrochemical sensor, not on a major surface. The Examiner views claim 169 differently. Kovacs teaches a body 124 that has a first major surface (where electrode tips 103 and 132) are located) and a second major surface (near where reference numeral 36 is located). (Fig. 10 of Kovacs). The first major surface is generally planar, slightly convex, and has rounded edges. The electrochemical sensing region 128 encapsulates the first major surface and thus is "on the first major surface" including that portion of the first major surface that is spaced away from the rounded edges (the center of the first major surface where the electrodes are located).

In regard to claim 170, the Applicant has argued that Kovacs and Dorman do not teach a body, wherein the sensing region is located on a major surface of the body and wherein said major surface comprises a continuous curvature substantially across the

entire surface of the body. The Examiner respectfully disagrees. Kovacs teaches a body 124 that has a major surface (where electrode tips 103 and 132) are located. (Fig. 10 of Kovacs). The major surface is a continuous curvature substantially across the entire surface of the body as seen in Fig. 10 of Kovacs since the major surface is essentially a curved end cap of the generally cylindrical shape. Kovacs further teaches a sensing region 128 encapsulating the first major surface and thus is "located on the first major surface." The Applicant's further assertions that Dorman does not teach a device with a sensor and thus does not address the deficiencies of Kovacs are not persuasive. Dorman is relied upon for the teaching that biocompatible epoxy is a suitable material (column 4, lines 14-16 of Dorman) for the invention of Kovacs and it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the biocompatible epoxy of Dorman since a material is required for the housing and Dorman teaches one such material.

In regard to claims 131 and 143-144, although there are new grounds of rejections, the Examiner would like to address the Applicant's argument that the Beck reference is non-analogous art. The Applicant correctly stated that a reference is a basis for rejection if the reference is reasonably pertinent to the particular problem with which the inventor was concerned. The Applicant admits that selecting an appropriate geometry for a device is a concern. Beck teaches that when selecting a shape of an implantable device sharp corners are to be avoided. (column 2, lines 51-56 of Beck). Thus, Beck is directly addressing a problem of concern in implantable devices (i.e., shape limitations on implantable devices) and, consequently, addressing a problem of

concern to the inventor. The Applicant's contention that Beck has no interest in selecting an appropriate geometry for a device that requires transport of analytes in vivo, such that the healing of the host tissue around the device is optimized, thereby minimizing variability, increasing transport of analytes, and controlling motion artifact in vivo is irrelevant. One with ordinary skill in the art faced with the task of selecting an appropriate geometry for an implanted device would look to Beck for the teaching that sharp edges are to be avoided since it is directed to the problem of selecting an appropriate geometry.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Kremer whose telephone number is 571-272-4727. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew Kremer
Assistant Examiner
Art Unit 3736

ERIC F. WINAKUR
PRIMARY EXAMINER